# Summary Minutes of the U.S. Environmental Protection Agency

# Chemical Assessment Advisory Committee Augmented for the Review of the Draft IRIS Benzo[a]pyrene Assessment (CAAC-Benzo[a]pyrene Panel)

Public Meeting April 15 – 17, 2015 Washington, DC

**Purpose:** To peer review the EPA's *Toxicological Review of Benzo[a]pyrene (External Review Draft – September 2014)* 

# **Meeting Participants:**

# CAAC-Benzo[a]pyrene Panel Members (See Roster):

Dr. Elaine Faustman, CHAIR Dr. Maureen Lichtveld

Dr. Scott Bartell Dr. Abby Li

Dr. Ronald Baynes Dr. Barry McIntyre

Dr. Annette Bunge Dr. Bhagavatula Moorthy

Dr. Scott Burchiel
Dr. Anna Choi
Dr. Anna Choi
Dr. Kenneth M. Portier
Dr. John DiGiovanni
Dr. Kenneth Ramos
Dr. Joanne English
Dr. Stephen M. Roberts

Dr. Joanne English

Dr. Stephen M. Roberts

Dr. William Michael Foster

Dr. Chris Gennings

Dr. Stephen M. Roberts

Dr. Richard Schlesinger

Dr. Leslie T. Stayner

Dr. Helen Goeden

Dr. Sean Hays

Dr. Charles Vorhees

Dr. John Kissel

Dr. Christi Walter

Dr. Ed Levin

SAB Staff Office: Dr. Diana Wong, Designated Federal Officer

Mr. Christopher Zarba, Director, Science Advisory Board Staff Office Mr. Thomas Brennan, Deputy Director, Science Advisory Board Staff

Office

**Other Attendees**: see Attachment A.

#### Meeting Materials and Meeting Webpage:

The materials listed below may be found on the meeting webpage at:

https://yosemite.epa.gov/sab/sabproduct.nsf/a84bfee16cc358ad85256ccd006b0b4b/32619301836a190d85257db2005f2b69!OpenDocument&Date=2015-04-15

- Agenda
- Federal Register Notice

- Charge Memos
- Review Documents
- Agency-provided Background Material
  - Table of public comments submitted on the IRIS Toxicological Assessment of Benzo[a]pyrene
- Agency Briefing Material
  - o EPA Presentation on Draft IRIS Assessment of Benzo[a]pyrene
- Committee-Developed or Provided Background Material
  - Compilation of Slides developed as Draft Responses to Charge Questions based on discussion on April 17, 2015
- Committee Members Comments
- Presentation by Registered Public Speaker
  - o Oral Comments by Annette Rohr, Electric Power Research Institute
  - Oral Comments by Brian Magee, on behalf of American Petroleum Institute, Asphalt Institute, and Pavement Coatings,
  - o Oral Comments by Anne LeHuray, Pavement Coatings Technology Council
- Public comments submitted to the SAB Staff Office
  - Anne LeHuray email dated May 19, 2015 on Systematic Review of Primary Skin Cancer by Dr. John Spinelli
  - Electric Power Research Institute on IRIS Toxicological Review of Benzo[a]pyrene
  - Utility Solid Waste Activities Group on 2013 Draft Benzo[a]pyrene Assessment Not Addressed in 2014 Draft BaP Assessment/Appendix G
  - American Coke and Coal Chemical Institute and Others on EPA IRIS Toxicological Review of Benzo[a]pyrene
  - American Coke and Coal Chemicals Institute and Others Supplemental Tables to Public Comments
  - American Coke and Coal Chemicals Institute and Others Cover Letter for Submitted Comments
  - o Anne LeHuray on Public Comments on EPA IRIS Toxicological Review of Benzo[a]pyrene Not Addressed in 2014 Draft Appendix G
  - Electric Power Research Institute on Examination of the Sources of Polycyclic Aromatic Hydrocarbon (PAH) in Urban Background Soil
  - Electric Power Research Institute on Polycyclic Aromatic Hydrocarbons (PAHs) in Surface Soils in Western New York
  - Electric Power Research Institute on Polycyclic Aromatic Hydrocarbons (PAHs) in Surface Soil in Illinois
  - o Public Comments from The Utility Solid Waste Activities Group
- List of Registered Public Speakers

# **Meeting Summary**

The discussion followed the plan presented in the meeting agenda.

# WEDNESDAY, APRIL 15, 2015

# **Opening Remarks**

Dr. Wong convened the meeting at 9:00 a.m. She explained that the SAB is an independent, expert federal advisory committee chartered under the authority of the Federal Advisory Committee Act (FACA). The SAB is empowered by law, the Environmental Research, Development, and Demonstration Authorization Act (ERDDAA), to provide advice to the EPA Administrator on scientific and technical underpinnings of the EPA's decisions. FACA and EPA policy require that SAB meetings be announced to the public in the Federal Register and that substantive deliberations, and interactions with EPA and the public, be conducted in open sessions where a DFO is present to ensure that the requirements of FACA are met. FACA also requires that advisory committees provide an opportunity for public comment. Dr. Wong noted there were two opportunities for public comment noted on the meeting agenda. The agenda included a public comment session on Wednesday for the 4 members of the public who had registered in advance with the SAB Staff Office to make oral comments. There would be another opportunity on Friday afternoon for the public to provide brief clarifying remarks. Members of the public also provided written comments that had been posted on the SAB website and circulated to panel members.

Mr. Christopher Zarba, the Director of the SAB Staff Office, welcomed and thanked panel members for their willingness to serve on this panel. Dr. Wong turned the meeting over to Dr. Faustman, Chair of the CAAC-BaP Review Panel.

Dr. Faustman reviewed the agenda and asked panel members to briefly introduce themselves. She then invited the EPA representatives to begin their presentations. Dr. Vince Cogliano thanked the Panel for their review of the assessment and provided the history of the peer review of the BaP assessment. He also explained that the IRIS program is developing a handbook that will change the preamble of the draft assessment.

Ines Pagan from EPA's Office of Air Quality and Planning (OAQPS) spoke on the phone to explain BaP is one of the risk drivers for the National Air Toxics Assessment. Update of the BaP assessment is important for EPA to develop a screening level.

Kathleen Newhouse, the assessment manager, then presented the key aspects of the BaP assessment and answered questions from the panel. The EPA presentation can be found on the meeting webpage.

Break

#### **Public Comments**

Dr. Faustman asked members of the public who had registered to provide comments to the panel to begin their presentations. Four individuals had registered to present oral comments at the meeting (see Appendix B). Comments from these speakers may be found posted on the meeting webpage.

On behalf of the Pavement Coatings Technology Council, Dr. Anne LeHuray commented that 1) literature search for the BaP assessment should include keywords focused on epidemiology or other human exposure studies; 2) the draft hazard assessment should be revised using systematic review techniques with additional attention to the quality and risk of bias of occupational and therapeutic exposure studies; 3) EPA should consider the coal tar pharmaceutical literature in conjunction with occupational exposure studies of PAH-exposed industries to evaluate whether BaP is a human dermal carcinogen; 4) existing evidence does not support classification of BaP as a human carcinogen. Dr. LeHuray's oral statements can be found posted on the meeting webpage.

On behalf of the American Petroleum Institute and the Pavement Coatings Technology Council, Dr. Brian Magee commented that the proposed dermal slope factor (DSF) does not pass validation tests. The DSF predicts that 100% of the observed hand cancer rate in the white population is due to touching BaP-toxic equivalent in char-broiled meats and urban soils. Dr. Magee's oral statements can be found posted on the meeting webpage.

On behalf of the Electric Power Research Institute, Dr. Annette Rohr commented on the phone that there is a lack of real-world validation of cancer risks presented in the IRIS assessment and that mouse skin tumors induced by PAHs contain a distinct and separate mutational signature, which is not seen in human skin tumors. Dr Rohr's oral statements can be found on the meeting webpage.

On behalf of the Utility Solid Waste Activities Group, Dr. Chris Saranko commented that BaP is a risk driver for cleanup of many sites which are the subject of remedial action. Use of the proposed DSF will result in unrealistic risk levels and will drive unattainable remediation targets. Written comments submitted by Utility Solid Waste Activities Group can be found on the meeting webpage.

#### Lunch

The Panel began discussion of response to charge questions after lunch.

#### **Charge Question #1 – Literature Search**

The panel agreed that the literature review process was well described and documented. Some keywords have focused on what was already known, but not what was not known. Review of references within the primary and secondary literature can be used to identify potentially relevant publications. Secondary literature searches can be conducted for additional effects or specific data gaps. EPA also needed to clearly define their criteria for study exclusion and inclusion. To increase transparency, the panel suggested EPA include a table in the appendix that listed excluded studies and the reason for their exclusion. The panel found the requirement of a direct measure of BaP exposure was too restrictive for epidemiology studies as these studies could be relevant for hazard identification. The panel also pointed out that *in vitro* studies appeared to be lacking.

# **Charge Question #2 – Hazard Identification**

# #2a – Developmental Toxicity

The panel agreed that human, animal and mechanistic studies support the conclusion that developmental toxicity and developmental neurotoxicity are human hazards of BaP exposure. The panel noted that Chen et al. (2012), the key study identified by the EPA, has both strengths (e.g. 10 M/10F from 40 litters; testing multiple dose levels of BaP; administered BaP by gavage; use multiple behavior tests) and weaknesses (e.g. Morris Water maze swim speed was not measured on learning trials; litter randomization and pup rotation among dams was raised as a concern because of its unknown effects). Panel members discussed the strengths and weaknesses of Chen et al. (2012) and agreed when the study was looked at as a whole, strengths outweighed weaknesses. There was clear dose-response in effect levels, and the effects are consistent with other studies. Also, instead of relying only on the Elevated Plus Maze data, the panel agreed all the data in Chen et al. (2012) should be taken into account collectively and viewing them in their totality as evidence of a developmental neurobehavioral effect of BaP exposure. The panel also noted that BaP is a teratogen and BaP exposure *in utero* has been demonstrated to cause fetal death and affect fetal sperm cells.

# #2b – Reproductive Toxicity

The panel agreed that available human, animal and mechanistic studies support EPA's conclusion that BaP is a male and female reproductive toxicant.

However, the challenge is in the selection of critical study and consideration of additional endpoints. The panel suggested that EPA should examine literature for dose-response effects on ovarian follicle counts, and consider impact of BaP genotoxic effects on germ cells with respect to increased DNA damage and mutagenesis. Also, EPA should provide context as to the applicability of the inflammatory cervical response described in Gao et al. (2011) for BMD/RfD derivation.

#### #2c – Immunotoxicity

The panel agreed with EPA's conclusion that immunotoxicity is a potential human hazard of BaP exposure.

The panel commented that the immunotoxicity datasets for BaP are limited because rats were utilized rather than preferred mouse models. No sensitive functional assays, such as the T-dependent antibody response were performed. Thymic atrophy is a relatively insensitive endpoint in mice and rats, resulting in a low confidence RfD. Immunotoxicity of BaP is due to a combination of genotoxicity (DNA adducts and p53-induced cell death), and non-genotoxicity.

#### #2d – Cancer

The panel agreed that BaP is a human carcinogen. There is strong evidence that PAH exposures cause lung cancer in coke oven workers. But because humans are not exposed to BaP alone, it is not possible to establish causality based on epidemiological studies alone. By the EPA-defined secondary criteria (involving similar mode of action and mechanistic events in humans and animals), there is sufficient evidence for the carcinogenicity of BaP in

humans. Coal tar treatment for psoriasis patients were largely negative. However, the panel did not believe these studies can be used to argue against the carcinogenicity of BaP. The panel also agreed that BaP caused cancer primarily through a mutagenic mode of action. Metabolism via the diol-epoxide pathway links BaP exposure to carcinogenesis through formation of a stable N2-deoxyguanine adduct, the mutagenic properties of which are well documented. Because BaP is a complete carcinogen, mechanisms beyond mutagenesis may also contribute to tumor induction.

# #2e – Other Toxicity

The panel agreed that available evidence presented does not support liver, kidney, and hematological effects as human hazards. However, available evidence does support forestomach toxicity in rodents is indicative of potential human hazard; and that cardiovascular toxicity and adult nervous system toxicity are potential human hazards.

# #3b – Inhalation Reference Concentration (RfC)

The panel found the proposed RfC did not have scientific validity as the database is too weak. The panel was concerned that the proposed RfC was only based on one study. (However, a panel member pointed out it was not the first time RfC was based on only one study in IRIS.) In addition, adverse effects were observed in all 3 concentrations in the study. The Lowest-Observed-Adverse-Effect-Level (LOAEL) may not be a true LOEL. EPA used an uncertainty factor of 3 to address residual uncertainty for interspecies extrapolation may be too low. Furthermore, the rationale for not employing a benchmark dose (BMD) approach to derive the point of departure is unclear.

The meeting recessed at approximately 5:30 p.m. until the following morning. Writing teams for various charge questions met to prepare summary slides for presentation on Friday, April 17.

# THURSDAY, APRIL 16, 2015

# #3b – Inhalation Reference Concentration (RfC) (continued)

The panel commented that the quality of the critical study, Archibong et al. (2002), was low to medium, and the death of pups was a serious endpoint. A panel member mentioned given the particle sizes used in the key study, the regional deposited dose ratio (RDDR) adjustment did not adequately account for interspecies differences in particle deposition in the respiratory tract and systemic toxicokinetics. Therefore, EPA's application of an UF of 3 to address residual uncertainty in extrapolating from animal to humans was inadequate. The composite uncertainty factor for the proposed RfC was 3000, which was the maximum composite uncertainty factor allowed.

The panel recommended EPA to also consider Wu et al. (2003) and Archibong et al. (2012) which described effects on birth-index data and mean number of pups born, respectively for RfC calculations. EPA should explore if these studies are amenable to BMD approaches.

# **Charge Question 3a – Oral Reference Dose (RfD)**

The panel discussed if Chen et al. (2012) was the best study to use to derive a RfD. Chen et al. (2012) has both strength and weakness (see discussion on April 15). The panel agreed that the overall finding in the study suggested neurobehavioral effect of BaP and supports the choice of the critical endpoint. The panel also recommended EPA to consider reproductive endpoints. Cervical hyperplasia and cervical inflammation from Gao et al. (2011) should be included in Table 2-3. Given significant limitations, decrease in ovary weight in rats from Xu et al. (2010) should not appear in Table 2-2. For application of uncertainty factors, the panel recommended EPA to consider application of bw<sup>3/4</sup> adjustment for extrapolation from neonate animal to neonatal human (not adult human). EPA should further justify the application of a database uncertainty factor of 3.

#### **Break**

# Charge Question 3c - Oral Slope Factor

The panel agreed that the two selected lifetime oral carcinogenesis studies were well done and appropriate for dose-response modeling. However, only one study (Beland and Culp, 1998, using female B6C3F1 mice) was used for oral slope factor derivation rather than using both studies. The rat study has more tumor sites. Mice is more sensitive to forestomach tumors and the mouse study only used female mice. The panel recommended EPA should consider averaging over both studies (e.g. simple averaging or meta-analysis) if no biological basis exists for choosing the mouse study versus rat study. The panel also questioned whether alimentary tract tumor sites should be scaled using EPA's cross-species allometric scaling methodology of BW<sup>3/4</sup>.

#### Lunch

#### **Charge Question 3d – Inhalation Unit Risk**

The panel commented that there was only one lifetime inhalation bioassay in male hamsters (Thyssen et al. 1981). Respiratory tract and pharynx tumors were found in exposed animals. Human epidemiology studies associated with PAH occupational exposures of aluminum smelter workers found increase in lung and bladder cancer, and added support to the hamster study. In addition, main features of the hamster study were replicated in a subsequent report (Pauluh et al. 1985), adding confidence in the results of this single study.

The panel agreed with EPA that the multistage Weibull model is preferable due to incorporation of time-to-tumor data, However, supplemental analysis using other doseresponse models should be conducted to help further support the use of the unit risk derived from the multistage-Weibull model. The panel also recommended EPA consider selection of occupational studies (or meta-analysis of occupational studies) to develop unit risk estimates for inclusion in Table 2-9.

#### **Break**

#### **Charge Question 3e – Dermal Slope Factor**

The panel found the proposed dermal slope factor (DSF) and the proposed method for cross-species scaling to be not sufficiently supported scientifically.

Regarding choice of studies for developing the DSF, the draft assessment reviewed 10 mouse skin tumor bioassays and Sivak et al (1997) study on male C3H/HeJmice was selected as the principal study for derivation of the DSF. Other skin cancer bioassays (Nesnow et al. 1993, and Levin et al. 1977) were mentioned but excluded for further analysis. The panel did not agree with the rationale for exclusion. The panel found Sivak et al. (1997) to be a well conducted study with clear dose-response, and mice is the most sensitive species. However, the study was based on a single sex and single mouse strain. The panel commented that EPA should combine results from the different studies shown in Table 2-11 to strengthen the derived DSF.

The panel discussed the choice of dose metric. The draft assessment stated that mass rather than mass/area can be used as the appropriate dose metric for cancer risk at "low doses" of BaP. The basis for low dose assumption that the mass of BaP was the appropriate dose metric for calculating the DSF was not provided in the draft assessment. A panel member commented that information supporting this has to come from dermal absorption, and the basis for cancer risk is from dermal absorption. The panel did not believe there are any empirical data available to inform a choice between these two dose metrics or to select another.

The panel then discussed cross-species scaling of the dermal slope factor in the mouse to obtain the dermal slope factor in humans. The panel found the draft assessment used BW<sup>3/4</sup> allometric scaling which may not be applicable. Differences between mouse and human skin should be considered, such as thickness of and metabolic rates in the target tissue (i.e., the viable epidermis layer).

The panel also discussed the relevance of epidemiologic studies of therapeutic use of coal tar preparations on psoriasis patients. The panel agreed these studies did not provide an adequate basis for either hazard identification or the derivation of a dermal slope factor, due to uncertainties regarding the PAH dose and that psoriasis patients shed skin at a much faster rate than normal. It would be more useful to review thoroughly the evidence for skin cancer in occupational studies of coke, steel and iron, coal gasification and aluminum workers given their relevance for evaluating the appropriateness of using the mouse based risk assessment model for predicting skin cancer risk in humans.

The panel agreed that cancer risk calculation should be based on the absorbed dose; i.e. cancer risk = DSF x absorbed dose. There are studies in literature of dermal absorption measurements from BaP contaminated soils.

The meeting recessed at approximately 5:30 p.m. until the next morning. The writing teams for various charge question met to prepare summary slides for presentation.

# **FRIDAY, APRIL 17, 2015**

Charge Question #3f – Age-dependent adjustment factors for cancer

The panel agreed that the proposed use of age-dependent adjustment factors is justified since available mechanistic studies in human and animals support a mutagenic mode of action for BaP-induced cancers. BaP is an example in EPA's Supplemental Cancer Guideline.

### Charge Question #5 – Appendix G

In response to the panel's comments that EPA did not provide a summary table in the assessment of all public comments received, as well as major public comments that EPA responded to in Appendix G, the EPA provided SAB on April 15 a summary table of public comments which can be found on the meeting webpage.

The panel agreed most scientific issues raised by the public, as summarized in Appendix G, were adequately addressed. However, the panel did not agree with EPA's response and offered its opinion on metric to characterize results in the elevated maze; anxiety-like effects as a critical effect; cross-species scaling of DSF, appropriate dose metric for BaP dermal carcinogenicity, and appropriate dermal bioavailability of BaP from soil. The panel supports groundtruthing calculations for the proposed DSF. One panel member commented that about 80% of skin cancer is not reported.

# **Charge Question #4 – Executive Summary**

The panel found that major conclusions were clearly and adequately presented in the executive summary and made several suggestions for improvement.

#### Lunch

Panel members brought back lunch and had a working lunch to finish their summary slides.

#### **Next Steps:**

Before presentation of slides by writing teams leaders for different charge questions, Dr. Wong provided schedules for next steps.

On April 24 – 1 week, revised individual comments are due

On May 15 - 4 weeks, written response to charge questions from writing groups are due

By the end of July (7/27), the draft SAB report will be posted on the SAB website.

On August 21 and September 2 – the panel will deliberate on the draft report during these two public teleconferences.

Dr. Faustman then asked the leaders of writing teams to present their summary slides for panel discussion. The summary slides of draft responses to charge questions that were revised based on panel discussion can be found at the link below:

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# **Brief Clarifying Comments**

At 1:40 pm, registered speakers from the public had another opportunity to provide brief clarifying comments.

Chris Saranko of GeoSyntec commented it is important to get science right. IRIS needs to produce assessments that are scientifically defensible. Deficiencies in the draft BaP assessment, especially the DSF, has to be made more rigorous.

Nancy Beck of American Chemistry Council thanked the panel's discussion, and commented that although EPA had previously quantified cancer risk using forestomach tumors, these tumors should be evaluated on a case by case basis.

Anne LeHuray of Pavement Coating Technology Council asked the panel to consider how her comments can be useful. She also commented that primary literature on occupational skin cancers did not find coke oven workers with skin cancer in modern settings.

Kevin Bromberg of the Small Business Administration commented that the purpose of comments from the panel is for EPA to do a better job.

Samantha Jones of EPA's IRIS program thanked the panel and commented that derivation of a dermal slope factor involves many complex issues.

The panel continued with discussion of summary slides, and finished about 4:30 pm. The panel were asked to revise the slides based on panel deliberation, and submit the revised slides to the DFO by April 22.

Dr. Faustman and Mr. Zarba thanked the Panel and Dr. Wong adjourned the meeting at approximately 4:30 pm.

On Behalf of the Committee,
Respectfully Submitted,
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/s/
Diana Wong, Ph.D.
Designated Federal Officer
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Cardification Trans
Certified as True:
/s/
Elaine Faustman, Ph.D.
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Chair, SAB CAAC-BaP Review Panel

NOTE AND DISCLAIMER: The minutes of this public meeting reflect diverse ideas and suggestions offered by committee members during the course of deliberations within the meeting. Such ideas, suggestions, and deliberations do not necessarily reflect definitive consensus advice from the panel members. The reader is cautioned to not rely on the minutes represent final, approved, consensus advice and recommendations offered to the Agency. Such advice and recommendations may be found in the final advisories, commentaries, letters, or reports prepared and transmitted to the EPA Administrator following the public meetings.

# **Attachment A. Other Attendees**

# a. List of persons who attended the meeting in person:

Name	Affiliation
Resha Putzrath	Navy and Marine Corps Public Health Center
Patrick Beatty	American Petroleum Institute
Anne LeHurray	Pavement Coating Technology Council
James Kim	OMB
LeeAnn Sinagoga	Tetratech
Nancy Beck	American Chemistry Council
Vince Cogliano	EPA
Kathleen Newhouse	EPA
Susan Reith	EPA
Linda Philips	EPA
Karen Hogan	EPA
Samantha Jones	EPA
Ken Olden	EPA
Glinda Cooper	EPA
Roxana Weil	FDA - CTP
Keith Salazar	EPA
Gina Perovich	EPA
Allison Foley	Venable LLP
Rayna Laiosa	PSE&G
Catherine Gibbons	EPA
Jason Fritz	EPA
Ted Berner	EPA
Xabier Arzuaga	EPA

Chris Saranko	GeoSyntec
Raghu Nath	EPA
Margaret Pratt	EPA
Katherine Super	Tetra Tech
Paul White	EPA
Pat Rizzuto	Bloomberg BNA
Louis D'Amico	EPA
Kevin Bromberg	Small Business Administration
Yan-Xin Li	Law Student
Maria Hegstad	Inside EPA

# b. List of Persons who Registered to Attend the Meeting by Calling-In:

Brian Magee	Arcadia
Annette Rohr	EPRI
Sarah Donatelli	GeoSyntec
John Vandenberg	EPA
Todd Blessinger	EPA
Louis D'Amico	EPA
John Fox	EPA
Jim Kim	OMB
Norman Birchfield	EPA
Connie Meacham	EPA
Doug Covert	Hazardous Substance & Waste Management
_	Research
April Luke	EPA
Joe Frasca	ExxonMobil
Rayna Laiosa	PSE&G

Bridget O'Brien	Orise Fellow
Anita Meyers	Army Corps of Engineers
Channa Keshava	EPA
Neeraja Erraguntla	Texas Commission on Environmental Quality

# Attachment B.

# **List of Public Speakers**

# U.S. Environmental Protection Agency Chemical Assessment Advisory Committee (CAAC) Augmented for the Review of Draft IRIS Benzo[a]pyrene Assessment

# Public Comments on the Assessment – April 15, 2015

#	Speaker's Name	Organizational Affiliation(s)
1	Anne LeHuray	Pavement Coatings Technology Council
2	Brian Magee	On behalf of American Petroleum Institute, Asphalt Institute, and Pavement Coatings Technology Council
3.	Annette Rohr	Electric Power Research Institute
4	Chris Saranko	On behalf of the Utility Solid Waste Activities Group